

Introduction

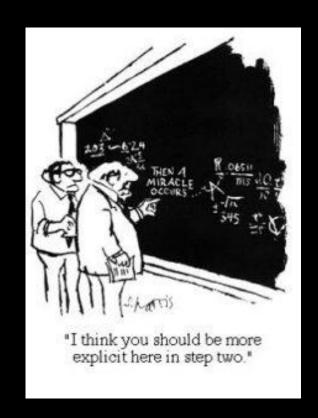
- So you want to do NASA funded research in a spaceflight analog?
- There are several things about participating in an HRP managed analog that are likely to be different from the way you normally do work in your laboratory.
- The purpose of this presentation is to highlight those differences and explain some of the unique aspects of doing this research.
- After the proposal and acceptance process the Investigator works closely with the Flight Analog team to ensure full integration of their study requirements into a complement.

Introduction II

- A complement is comprised of a group of studies requiring a common platform and/or scenario that are able to be integrated on a non-interference basis for implementation (HERA, :envihab bedrest, etc).
- Full integration of an individual study has three phases:
 - integration,
 - preparation, and
 - implementation.
- These phases occur in order with some overlap in the integration and preparation phase.
- The ISSMP-FA (FA) team integrates, plans, and implements analog study complements.

Phase 1: Integration

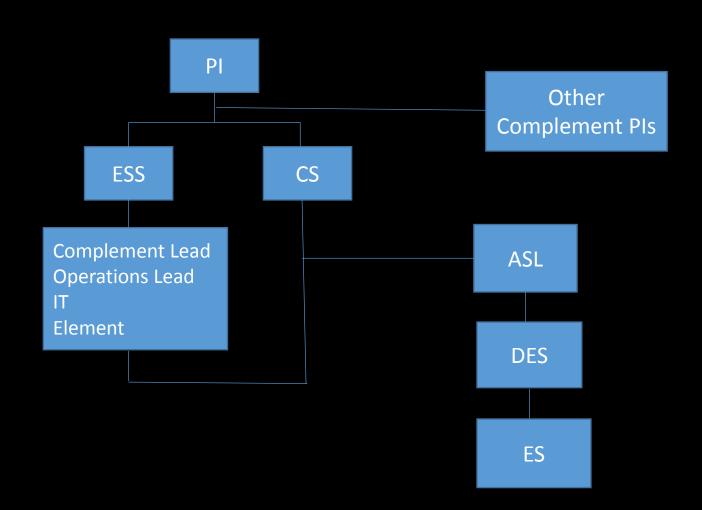
- Integration requires plasticity; investigators are asked to work closely with one another and the Flight Analog team to combine research studies into a single study plan.
- This goal of the study plan is to facilitate multiple study participation with minimal scientific impact to each individual study.
- The Flight Analog's team negotiates compromises for all parties and ensures the analog platform maintains the appropriate flight fidelity.



How do I Integrate?

- The key to efficient and effective integration is well defined requirements.
- ISSMP-FA works with the PI to identify and document study details and requirements for an individual study basis through the PI's specific science requirements document (SRD).
 - Note- it is important to inform ISSMP-FA of BOTH the ideal and minimum requirements....bad science is worse than no science
- Once SRDs are complete, ISSMP-FA combines all PI, Operational, and Platform requirements into a Complement Integrated Requirements Document (IRD). The IRD outlines and documents all individual and compliment research requirements for planning and implementation.

Who do I work with from ISSMP-FA?



PI: Principle Investigator

ESS: Experiment Support Scientist

CS: Complement Scientist ASL: Analog Science Lead

DES: Deputy Element Scientist

ES: Element Scientist

Individual Requirement Definition and Integration

- Individual requirements integration is the first step in ensuring that the research fits into an available analog platform or the Flight Analog team may provide information on structural study changes needed for participation in an analog platform
- Investigators need to understand exactly what their requirements are to produce scientifically relevant data and convey their "must have" needs to the Flight Analog team.
 - NOTE: Unclear or changing requirements make integration difficult and have negative direct effects on implementation of each study.
- The fluid nature of analog platforms allow for minor alterations to the operational structure, in some ways more flexible than flight.
- Participation in analog research requires flexibility from the investigator to ensure implementation of their research into a flight like analog platform.

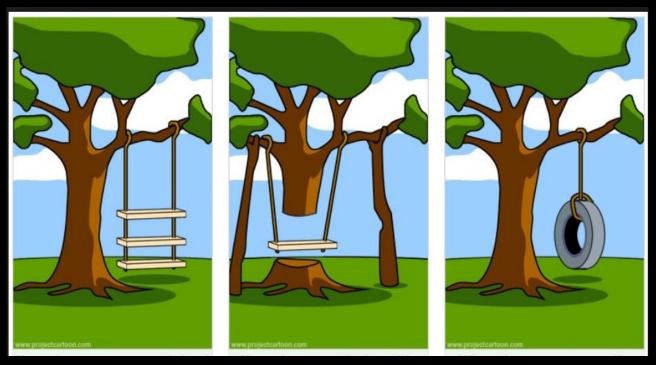
Requirement Documentation



- The process to document requirements is twofold, consisting of an initial individual requirements integration and then a complement requirements integration.
- Understanding the requirements in detail and early ensures that the science is not compromised by outside influences. This step is vital to the integration, preparation, and implementation phases.

Research Requirements

- Properly defining your research requirements and getting them documented, is critical to ensure successful integration and implementation of your study, but is often neglected by PI teams during the early integration phase.
- Requirements that are not documented, or are documented poorly are unlikely to be implemented, no matter how much you push.



How the PI described experiment.

How the team understood experiment.

What the PI really wanted.

What happens if I do not define my requirements well....







Keys to writing good requirements

- What do you "need" vs what would be "nice to have"
- Be as specific as possible and include any constraints associated with your testing
- Include a reasonable "window"
- Balance mission fidelity with science purity
- Screening inclusion/exclusion criteria
- Be aware of other science going on (attend IWGs)
- Make sure you know about other "constraints" of platform
- What hardware, software or consumables do you need?
 - Who will provide?
 - Who will collect (test subjects do not act as laboratory technicians)?
 - Do you have a local Co-I?

Common requirements/constraints that may impact science

- Sleep schedule
- Biological collections (especially fasting)
- Meal schedule
- Exercise
- Noise levels/distractions
- MRIs
- Ingestible devices
- Wearable technologies
- Personal hygiene activities



Final Integration

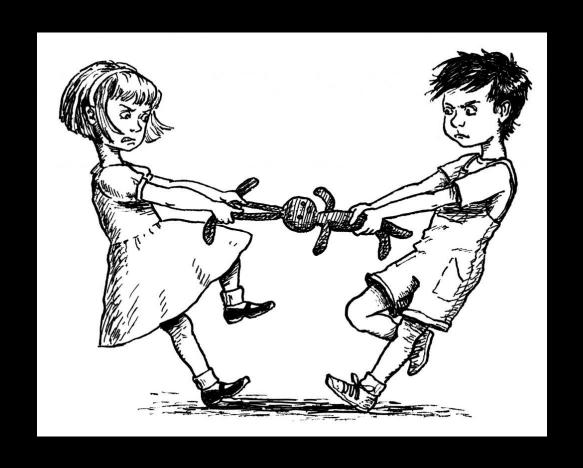
• Additional restrictions, limitations and constraints may be required by the analog in order to make all of the science work. Many studies need to be combined into each complement and there are a limited number of hours available for data collection. Through data/sample sharing, we can reduce the burden on the test subject, while usually avoiding significant science impacts. Restrictions on food, exercise, medications and sleep cycle are important to consider for your

research.



Data Sharing

(aka, What! you mean I have to share my data?)



Data Sharing

- A campaign-specific Data Sharing Plan (DSP) will be developed by ISSMP-FA
- The DSP will define how the requested data are to be shared between PIs
 - The DSP enables all PIs to view the data collected during the complement.
 - It is up to the PIs to coordinate and outline how the data will be shared and negotiate publishing rights, etc.
- Once agreed upon, all PIs and ISSMP-FA will sign and ISSMP-FA will submit to IRB
- No data sharing specifics or amendments to your stand-alone IRB will be required and any changes will be handled by ISSMP-FA and submitted to the IRB
- All data generated for a NASA study, or provided to a NASA funded PI, shall be uploaded to LSDA

It should be noted that the sharing of data between investigations in no way abrogates the individual investigator's first right to publication of the data derived from their own investigation. It is imperative that data shared from other investigations be referenced in publications of recipient investigators in such a way as to maximally safeguard this right

Data Sharing II

Data Sharing:

- Data exchange documented in the DSP shall occur directly between investigators following test subject consent. Data distribution shall adhere to NASA security standards regarding subject privacy requirements
- FA will develop an initial DSP and distribute to the PI team for input and/or concurrence

Sample Sharing:

- Sample sharing (physiological samples, venipuncture) will be encouraged to minimize blood volumes and inconvenience to subjects.
- Sample exchange will be documented in the DSP and shall occur directly between investigators.
- Sample distribution shall adhere to NASA security standards regarding subject privacy requirements.

What's Expected from Me?

- Work with ISSMP-FA ESS to fully develop the SRDs
- Support campaign integration by providing timely input and feedback to ISSMP-FA IRD
- Submit Stand-alone Protocol to JSC IRB
 - This must include your home institution IRB approval as part of JSC IRB submittal
 - Must include your merit review and all data sharing in your submission any data you expect to share or receive
- Provide all hardware and software required for your testing
- Provide all training materials and procedures required for crew and mission operations
- Provide crew briefings, training, BDC support and mission support as needed
 - Mission support includes after hour support to address any off-nominal situations that may occur
- Conduct negotiations required for data sharing (e.g. publication rights, etc.)

Don't worry – we are here to help you effectively and efficiently reach your scientific goals!

Closing Remarks

